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A Novel Drug Management System in the Febuxostat versus Allopurinol Streamlined Trial (FAST): A description of a pharmacy system designed to supply medications directly to patients within a prospective multicenter randomized clinical trial.

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Keywords:	Clinical trials, drugs, investigational, internet, pharmacy, pharmaceutical services
Abstract:	<p>Background Trials of investigational medicinal products are required to adhere to strict guidelines with regard to the handling and supply of medication. Information technology offers opportunities to approach clinical trial methodology in new ways. This report summarises a novel pharmacy system designed to supply trial medications directly to patients by post in the Febuxostat versus Allopurinol Streamlined Trial (FAST).</p> <p>Method A bespoke web-based software package was designed to facilitate the direct supply of trial medications to FAST participants from a pharmacy based in the Medicines Monitoring Unit (MEMO), University of Dundee.</p> <p>Results To date, 65467 packs of medication have been dispensed using the system to 3978 patients. Up to 238 packs per day have been dispensed.</p> <p>Conclusions The Medicines Monitoring Unit FAST Drug Management System is an effective method of administering the complex drug supply requirements of a large scale clinical trial with advantages over existing arrangements. A low rate of loss to follow-up in the FAST trial may be attributable to the drug management system.</p>

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A Novel Drug Management System in the Febuxostat versus Allopurinol Streamlined Trial (FAST): A description of a pharmacy system designed to supply medications directly to patients within a prospective multicenter randomized clinical trial

Running Head: Postal drug supply to trial participants

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Abstract

Background: Trials of investigational medicinal products are required to adhere to strict guidelines with regard to the handling and supply of medication. Information technology offers opportunities to approach clinical trial methodology in new ways. This report summarises a novel pharmacy system designed to supply trial medications directly to patients by post in the Febuxostat versus Allopurinol Streamlined Trial (FAST).

Method: A bespoke web-based software package was designed to facilitate the direct supply of trial medications to FAST participants from a pharmacy based in the Medicines Monitoring Unit (MEMO), University of Dundee.

Results: To date, 65,467 packs of medication have been dispensed using the system to 3,978 patients. Up to 238 packs per day have been dispensed.

Conclusions: The Medicines Monitoring Unit FAST drug management system is an effective method of administering the complex drug supply requirements of a large scale clinical trial with advantages over existing arrangements. A low rate of loss to follow-up in the FAST trial may be attributable to the drug management system.

Keywords

Clinical trials, drugs, investigational, internet, pharmacy, pharmaceutical services

Background

Information technology offers opportunities to approach clinical trial methodology in new ways. This report summarises a novel pharmacy system designed to supply trial medications directly to patients in a primary care setting. Primary care-based clinical trials aim to provide answers with high external validity. However, conducting research in primary care has its own challenges. Recruitment and retention of general practitioners and their patients are significant rate limiting steps in the process of conducting a trial.¹ Minimising the potential financial and time burden on trial participants may increase recruitment and retention.² Trials of investigational medicinal products are required to adhere to strict guidelines with regard to the handling and supply of medication.³ A systematic literature search on the subject (online Supplementary Material 1) found only 2 reports of computerised investigational drug services set up in secondary and tertiary care facilities in North America.^{4, 5} The search failed to uncover reports of any similar systems designed for use in primary care research. The FAST study team have developed a system to streamline the handling of study drug that could be used as a model for other future drug trials.

Methods

The Febuxostat versus Allopurinol Streamlined Trial (FAST) is a prospective, randomised, open-label, blinded endpoint evaluation trial to compare the cardiovascular safety of febuxostat and allopurinol in patients with a diagnosis of gout.^{6, 7} The pragmatic

design allows the safety of the two drugs to be compared while permitting dose adjustments during the study, if required, usually for clinical reasons. Recruited patients in the UK and Denmark are randomised to receive either allopurinol or febuxostat along with medication for gout flare prophylaxis. The gout flare prophylaxis is supplied if required, in accordance with European League Against Rheumatism recommendations and is available in 4 forms: colchicine; naproxen with omeprazole or ranitidine; meloxicam with omeprazole or ranitidine; or diclofenac with omeprazole or ranitidine.⁸ (figure 1)

Medication supply is standardised across all centres taking part in this study. Patients recruited from all study centres are supplied their medication directly from a pre-approved registered pharmacy premises run by the Medicines Monitoring Unit at Ninewells Hospital, Dundee, UK. The study medication is supplied by post at regular intervals.

All FAST study medication is received, stored, labelled and distributed from the Medicines Monitoring Unit Pharmacy dispensary. A number of facilities are in place to allow this: (i) a temperature-controlled bulk-store (capable of storing 23m³ or 18 pallets of investigational medicinal product); (ii) a temperature-controlled “buffer” store in the Hypertension; and (iii) an adjacent Medicines Monitoring Unit dispensary.

Nurses inform the dispensary by email when they have seen a patient at a follow-up appointment who requires a change to medication according to the study protocol. The

dispensary then accesses that patient's details via a pharmacy web portal and can determine what medications are required along with required information such as delivery addresses and their doctor's contact details. The order is then generated and filled ready for Royal Mail first class delivery. All medications are supplied in "mail friendly" packaging containing a study-specific bilingual (English & Danish) patient information leaflet with details of the relevant medication. The format and information contained is very similar to those provided with commercially available packs of these medicines.

The FAST drug management system

This bespoke software program tracks the stock of investigational medicinal products (allopurinol and febuxostat) and non-investigational medicinal products (gout flare prophylaxis medications and concomitant gastric protectants) used throughout the trial. The system controls drug supply management for patients in the FAST study.

The FAST drug management administrative system is web-based with real-time updating of stock levels and dispensing details. The system is used exclusively by staff engaged in the FAST trial. The key users are the trial superintendent pharmacist, a research pharmacist(s), and pharmacy technicians.

During development, the Microsoft Internet Explorer 9 browser was identified as the single platform for the interface, eliminating the need to target multiple browsers.

(More specific information about the hosting requirements of the system can be found in online Supplementary Material 2.)

All aspects of the drug supply process are automatically recorded on the FAST drug management system allowing an audit trail to be established.

User interface. The user interface of the FAST drug management system is a web application. Once a user is logged in, seven main areas of functionality are available to them: shipping, confirmation, dispensing, check, receipts, returns, and stock. A restricted access area is also available to the superintendent pharmacist that allows the creation of new system users. The user interface allows stock level monitoring. This facilitates simple spot checks and allows stock levels to be monitored and maintained.

Shipping and confirmation. When a new consignment of medication arrives on site, details of the shipping are entered into the user interface and the database is updated automatically. Each medication pack that arrives is assigned a unique barcode for use within the FAST drug management system. The confirmation page of the user interface then requires a second operator to confirm the details of the newly arrived medication before it is recognized as in stock and available for dispensing.

Dispensing, checking and receipts. Medicines are dispensed with the addition of a dispensing label which includes the medicine name, patient name, date of supply, standard safety warnings, the center-specific investigator's name and an instruction to

“use as directed on the patient direction form”. Patients are also supplied with a patient direction form, a receipt of supply form and a prepaid return mail polybag. All items issued to patients are barcoded to enable the subsequent dispensing check and to track returned receipt postcards and patient returned medication.

On selecting a patient, the required address labels are automatically printed (based on the number of packs of study medication required). The required medications for that patient are displayed on screen. The receipt postcard is scanned by the pharmacy technician followed by each medication pack in turn. Each product barcode is checked by the system to confirm that the correct product has been selected and to check that the product will not expire within 2 months of dispensing. Each time a suitable pack is scanned a dispensing label is automatically printed and immediately stuck to the pack. (figure 2)

A second dispensing stage requires another operative (pharmacist or pharmacy technician) to verify the medication packs selected by the initial user. This is done by scanning the box barcodes and comparing the boxes with the expected content products displayed. If the barcodes scan correctly, indicating that the pack(s) has been correctly assembled, and the second operative is satisfied that the products are correct, the dispensing is confirmed. The box is then considered “sent”. All medications delivered to patients are supplied with a postage-paid postcard that acts as a receipt. Returned receipt postcards are scanned and recorded in the system.

Patients are asked to return any unused medication from their previous delivery in the polybag provided. Returned product is logged by scanning the product pack barcode and entering the number of pills returned within.

Medication considerations in FAST

Medicines used in FAST are the investigational medicinal products: allopurinol, febuxostat; and the non-investigational medicinal products, used for gout flare prophylaxis and gastric protection: colchicine, naproxen, diclofenac, meloxicam, omeprazole and ranitidine. These medications are received from two different sources. Investigational medicinal products and some non-investigational medicinal products are supplied by the trial funder. The remainder of the non-investigational medicinal products are procured independently (via wholesale or local hospital pharmacy). The FAST drug management system allows these two different source pathways to be managed within one trial-specific system.

Results

At the time of writing, 65,467 packs of medication have been dispensed using the system to 3,978 patients. Up to 238 packs per day have been dispensed. During a 20 month analysis period, 25,568 supplies were made to patients in the UK and Denmark, comprising 38,250 individual packages. Only 46 of these were reported as failing to arrive, the majority of which had simply been delayed in transit. Only 8 packages could be considered lost during this 20 month period (0.31 per 1000 dispatched packages).

Initial supplies of study medication are mailed to participants on the day of randomisation and arrive within 1-2 days in the UK. Deliveries to Denmark have been predictably slower but arrive well within the 21 days required by the FAST study protocol. Subsequent repeat medication supplies are sent out a minimum of 8 days before they are required with additional time allowed for international delivery and busy postal periods e.g. Christmas.

A lack of unaccountable loss to follow-up of patients within FAST in the 3.5 years since the trial began may be attributable to the regular prompting that direct medication delivery provides. There have been 133 withdrawals from study treatment after randomisation in the same period (out of 3130 randomised) suggesting that participant acceptability of the drug delivery system compares favourably with more traditional methods.

Conclusions

The FAST drug management system has a number of advantages over more standard methods of clinical trial drug supply and distribution. The use of computer technology allows real-time monitoring of stock levels for the whole study at a glance. This reduces the chance of any stock problems interfering with the correct administration of medication according to study protocol. Direct supply of study drug to participants removes the requirement for study drug storage at multiple sites. This single central storage location thus allows efficiency savings in equipment, personnel and training. The

FAST drug management system was set-up to accept supply of study drug from more than one source. This could be scaled up to coordinate multiple drug sources for more complex trial requirements. The software adheres to European Union regulatory requirements for labeling of dispensed medication and can be simply modified to allow dispensing to non-English speaking trial participants. It is recognized, though, that non-Roman script would require more intensive software adaptation.

As participants in the FAST study receive their study medication directly to their home address they benefit from the convenience of post-box compatible delivery and the removal of the need to regularly visit a dispensing site throughout the study period. The system database can easily accommodate changes in address should participants move home during a lengthy study period. The use of individually barcoded packs and the printing of predetermined text which draws on patient details taken from the electronic case report form mean that dispensing errors are minimised.

Further research is ongoing into the potential cost savings of alternative supply mechanisms aiming to further reduce the amount of drug oversupply.

Discussion

As with any successful organizational change, the implementation of the FAST drug management system was borne out of a consensus agreement that a new way of handling study drug was required. Overcoming resistance to change relied on regular

communication between involved parties, and effective leadership to steer alterations to normal practice. The presence of an in-house software development team was fundamental in allowing the development of a system to meet the specific requirements of clinical trial study drug management.

The FAST drug management software is currently closed source and owned by The University of Dundee. Researchers wishing to produce such a system would require a software development team, working closely with pharmacy staff, and, a systems administrator to ensure smooth running and back-up.

Minimising missing data is important in any study. Long duration trials like FAST are particularly susceptible to loss to follow-up and withdrawals. We are encouraged that withdrawals from the trial so far have been relatively low when compared to the 6% median and 2-14% interquartile range reported by LOST-IT review.⁹

While the FAST study used investigational medicinal product, the system would also be capable of supplying licensed drugs in post-marketing studies. A facility to privately prescribe and dispense licensed medications that are not yet approved for National Health Service use could simplify post-marketing research.

The FAST drug management system has been demonstrated to be a safe and effective method of administering the complex drug supply requirements of a large scale

clinical trial. We propose that it can be used as a prototype in developing future clinical trials.

Abbreviations

FAST Febuxostat versus Allopurinol Streamlined Trial

Competing Interests

FAST is funded by an academic study grant from Menarini and sponsored by the University of Dundee.

Funding

The FAST study is supported by an academic study grant from Menarini.

Authors' contributions

AR wrote the initial draft of the manuscript. RF is the Superintendent Pharmacist for FAST, was the lead in devising the pharmacy system and helped to draft the manuscript. PM developed the software for the system. IM is a Principal Investigator in the FAST study and helped to draft the manuscript. TM is the Chief Investigator on FAST and came up with original idea for a computerised drug management system. He drove the project forward and helped to draft the manuscript. All authors read and approved the final manuscript.

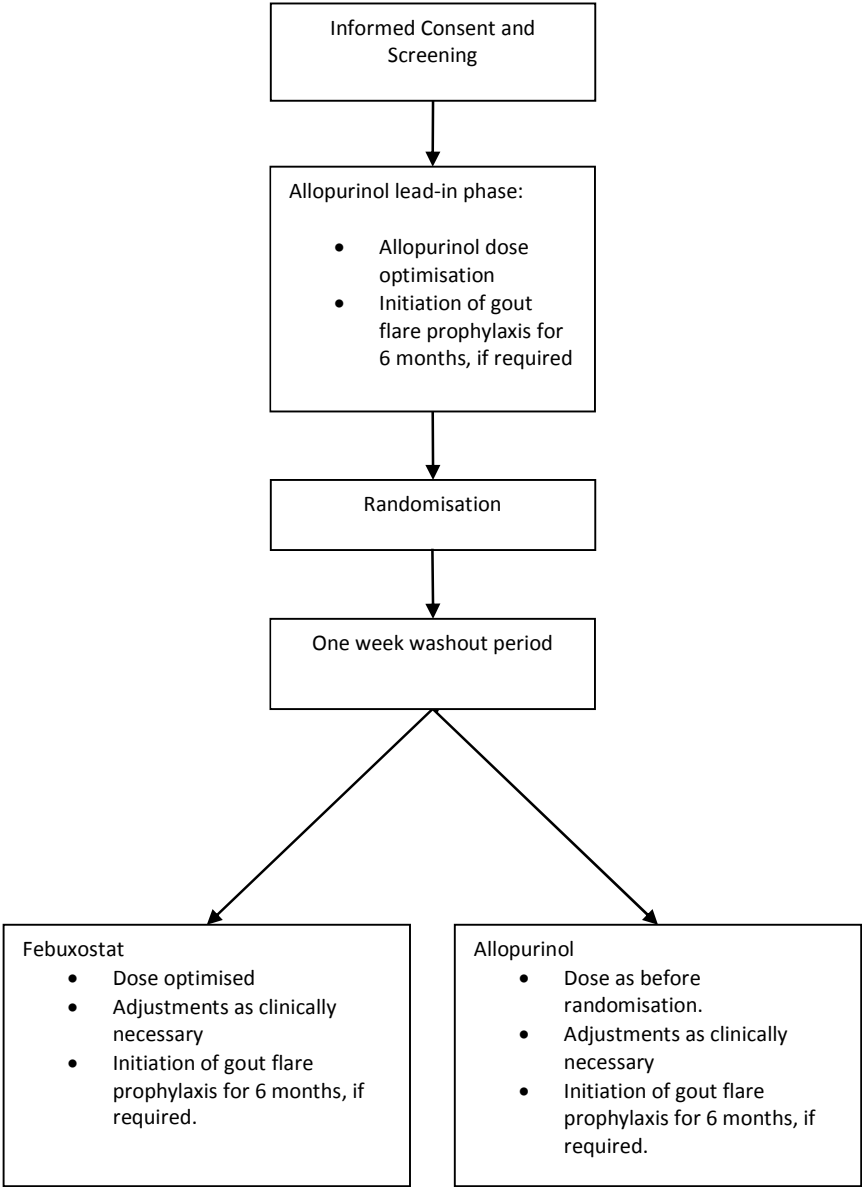
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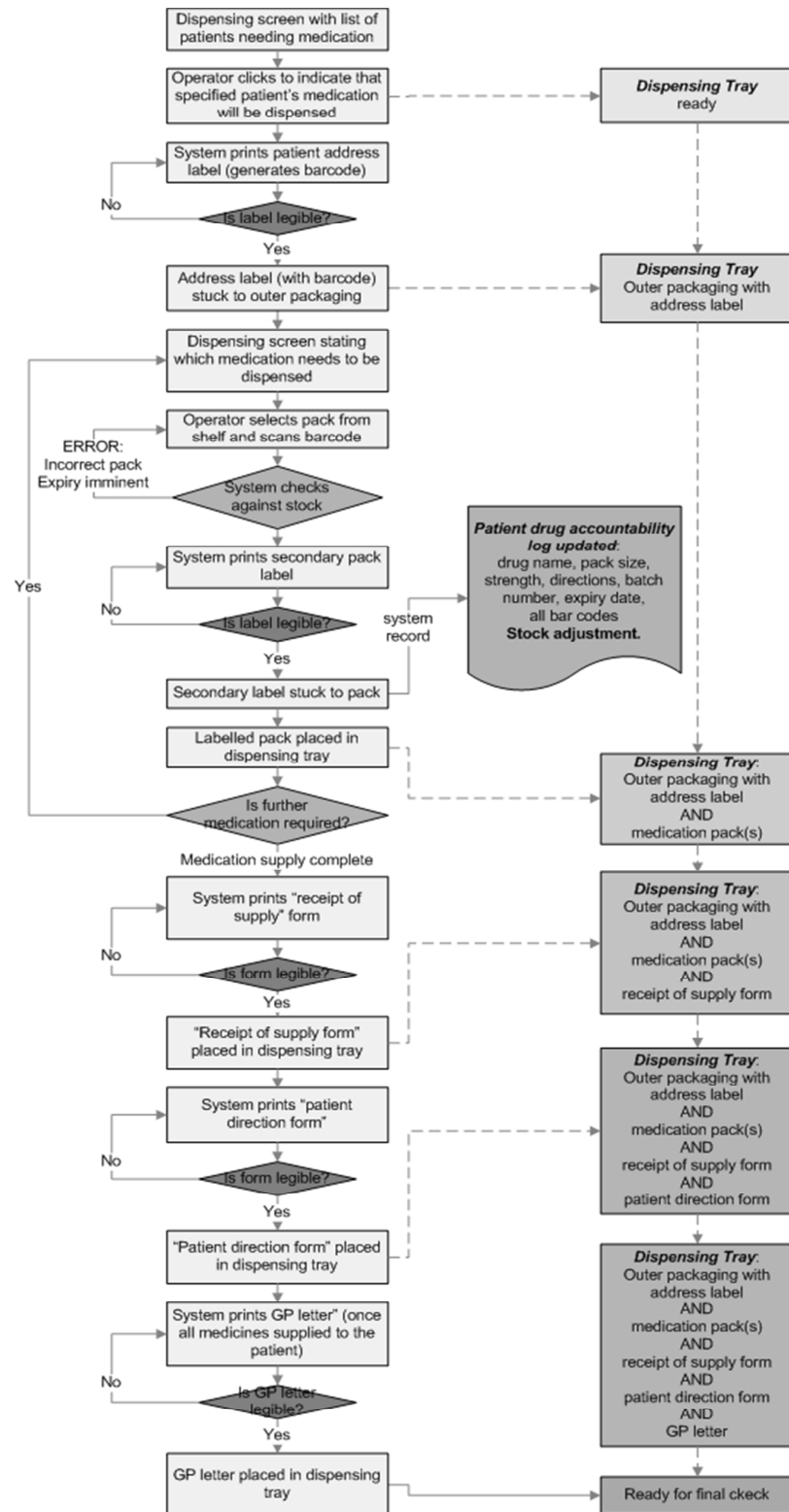
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Figure legend

Figure 1. FAST study flow diagram

Figure 2. FAST drug management system process diagram





FAST DMS Supplementary Material 1

Pubmed Systematic Literature Search Strategy

MeSH headings and keywords were determined using the NIH MeSH on demand website to analyse a description of the FAST DMS. (<http://www.nlm.nih.gov/mesh/MeSHonDemand.html>)

1. Search ((((((clinical trials as topic[MeSH Major Topic]) OR "clinical trial"[Title/Abstract]) OR "drug trial"[Title/Abstract]) OR "randomised controlled trial"[Title/Abstract])) OR research[Title/Abstract]

= 1038326 items found

2. Search (((("drugs, investigational/supply and distribution"[MeSH Major Topic])) OR "pharmaceutical services"[MeSH Major Topic]) OR "medicines management"[Title/Abstract]) OR "drug management"[Title/Abstract] AND "pharmacy"[Title/Abstract]

=7555 items found

3. Search (((("online systems"[MeSH Major Topic]) OR "electronic mail"[MeSH Major Topic]) OR "postal service"[MeSH Major Topic]) OR "online"[Title/Abstract]) OR "web-based"[MeSH Major Topic]

=55229 items found

4. Search ((#11) AND #18) AND #19

=29 items found

Date searched 2nd June 2015 UK time 13:41

Of the 29 items found that appeared to be relevant, only one was applicable[1]. A Pubmed search for similar items yielded only 2 more, one of which was relevant [2].

1. Iteen SA, Ceppaglia J. Investigational drug information through a hospitalwide computer system. American journal of hospital pharmacy 1992; 49: 2746-8.
2. Sweet BV, Tamer HR, Siden R, McCreddie SR, Gregory ME, Benner T, Tankanow RM. Improving investigational drug service operations through development of an innovative computer system. American journal of health-system pharmacy : AJHP : official journal of the American Society of Health-System Pharmacists 2008; 65: 969-73.

Supplementary Material 2**FAST Drug Management System – Hosting Requirements**Web Server

Dual-Core i5 (or better), running at 2Ghz (or faster), with 8Gb of RAM and 10Gb HDD.
Running Windows 7 and [ASP.net](#) 3.5.

Database

Minimum of Quad-Core i7 (or better), running at 2.4Ghz (or faster) with 16 Gb RAM, and 1Tb HDD (preferably with RAID 10 configuration for performance and resilience).

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Manuscript ID:	CT-15-0227.R3											
Funding Information:	Menarini Academic Study Grant											
Submitting Author:	<div> <input type="text" value="Rogers, Amy"/> <input checked="" type="checkbox"/> Save Rogers, Amy (proxy) </div> <hr/> <p> <i>primary affiliation</i> University of Dundee - Medicines Monitoring Unit and Hypertension Research Centre Division of Cardiovascular and Diabetes Medicine Ninewells Hospital and Medical School Dundee DD1 9SY United Kingdom of Great Britain and Northern Ireland T: 01382 383119 </p>											
Authors & Institutions:	<table border="0"> <tr> <td> Rogers, Amy proxy</td> <td> University of Dundee - Medicines Monitoring Unit and Hypertension Research Centre Division of Cardiovascular and Diabetes Medicine Ninewells Hospital and Medical School , Dundee DD1 9SY United Kingdom of Great Britain and Northern Ireland </td> </tr> <tr> <td> Flynn, Robert W V proxy</td> <td> University of Dundee - Medicines Monitoring Unit and Hypertension Research Centre Dundee United Kingdom of Great Britain and Northern Ireland </td> </tr> <tr> <td> McDonnell, Patrick G proxy</td> <td> University of Dundee - Medicines Monitoring Unit and Hypertension Research Centre Dundee United Kingdom of Great Britain and Northern Ireland </td> </tr> <tr> <td> Mackenzie, Isla S proxy</td> <td> University of Dundee - Medicines Monitoring Unit and Hypertension Research Centre Dundee United Kingdom of Great Britain and Northern Ireland </td> </tr> <tr> <td> MacDonald, Thomas M proxy</td> <td> University of Dundee - Medicines Monitoring Unit and Hypertension Research Centre Dundee United Kingdom of Great Britain and Northern Ireland </td> </tr> </table>		Rogers, Amy proxy	University of Dundee - Medicines Monitoring Unit and Hypertension Research Centre Division of Cardiovascular and Diabetes Medicine Ninewells Hospital and Medical School , Dundee DD1 9SY United Kingdom of Great Britain and Northern Ireland	Flynn, Robert W V proxy	University of Dundee - Medicines Monitoring Unit and Hypertension Research Centre Dundee United Kingdom of Great Britain and Northern Ireland	McDonnell, Patrick G proxy	University of Dundee - Medicines Monitoring Unit and Hypertension Research Centre Dundee United Kingdom of Great Britain and Northern Ireland	Mackenzie, Isla S proxy	University of Dundee - Medicines Monitoring Unit and Hypertension Research Centre Dundee United Kingdom of Great Britain and Northern Ireland	MacDonald, Thomas M proxy	University of Dundee - Medicines Monitoring Unit and Hypertension Research Centre Dundee United Kingdom of Great Britain and Northern Ireland
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Contact Author (populates the ##PROLE_AUTHOR_...## e-mail tags):	<div> <input type="text" value="Rogers, Amy"/> <input checked="" type="checkbox"/> Save Current Contact Author: Rogers, Amy (proxy) </div>											
Running Head:	Postal drug supply to trial participants											
Keywords:	Clinical trials , drugs, investigational , internet , pharmacy , pharmaceutical services											